Chapter 7 Other Health Services

Other ambulatory health services consist of primary, specialty, and supportive medical services provided on an outpatient basis, in contrast to services provided in the home or to persons who are inpatients. The term ambulatory care implies that patients must travel to a location outside the home to receive services that do not require an overnight hospital stay. This chapter describes several organizations which provide ambulatory care in Mississippi. In addition, this chapter discusses home health services in Mississippi.

700 Ambulatory Surgery Services

During FY 2016, the state's medical/surgical hospitals reported a total of 277,138 general surgical procedures. This number included 186,324 ambulatory surgeries, almost a 6.96 percent increase of the 174,198 ambulatory surgeries performed in hospitals during 2013. The percentage of surgeries performed on an outpatient basis in hospitals has risen from 63.4 percent in 2013 to 67.2 percent in 2016. Table 7-1 displays hospital affiliated surgery data by general hospital service area.

Mississippi licenses 19 freestanding ambulatory surgery facilities. Table 7-2 shows the distribution of facilities and related ambulatory surgery data. The 19 facilities reported 85,842 procedures during fiscal year 2016. Total outpatient surgeries (hospitals and freestanding facilities combined) comprised 99.05 percent of all surgeries performed in the state. The number of procedures performed in freestanding facilities was 30.97 percent of total surgeries in 2016.

Table 7-1
Selected Hospital Affiliated Ambulatory Surgery Data by General Hospital Service Area
FY 2016

			Ambulatory Surgeries /	Number of	Average Number of Surgical
General	Total	Number of	Total	Operating	Procedures
Hospital	Number of	Ambulatory	Surgeries	Rooms /	per Day /
Service Area	Surgeries	Surgeries	(Percentage)	Suites	Suite
Mississippi	277,138	186,324	67.2	467	2.37
1	7,810	4,751	60.8	19	1.64
2	32,386	20,805	64.2	46	2.82
3	18,887	14,483	76.7	31	2.44
4	24,964	17,536	70.2	44	2.27
5	88,863	57,891	65.1	153	2.32
6	22,442	16,367	72.9	40	2.24
7	17,680	16,317	92.3	35	2.02
8	23,617	14,472	61.3	43	2.20
9	40,489	23,702	58.5	56	2.89

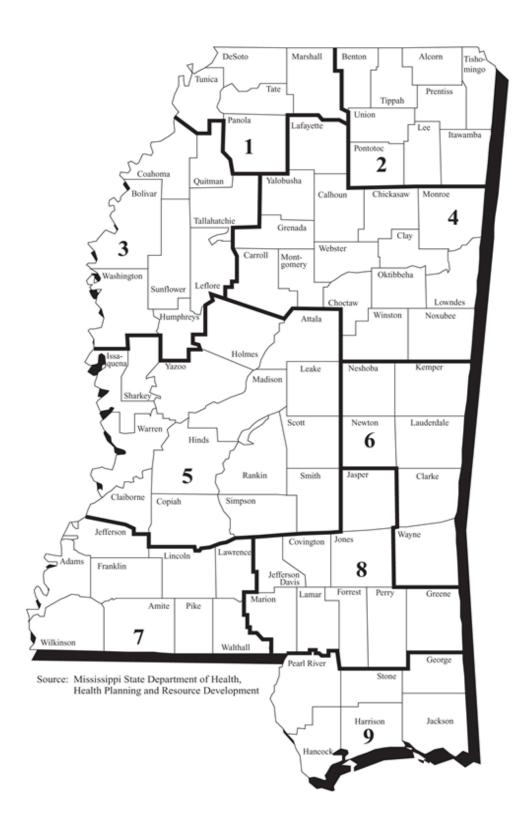
Table 7-2 Selected Freestanding Ambulatory Surgery Data by County FY 2016

Ambulatory Surgery Planning Area	County	Number of Freestanding Ambulatory Surgery Centers	Number of Ambulatory Surgeries Performed	Number of Operating Rooms/Suites	Number of Surgical Procedures Per Day/O.R. Suite
(ASPAs)	Mississippi	19	85,842	77	4.46
1	DeSoto	1	2,165	3	2.89
2	Lee	1	7,883	8	3.94
4	Lafayette	1	3,609	4	3.61
5	Hinds	3	23,415	13	7.20
5	Rankin	2	11,973	10	4.79
6	Lauderdale	1	4,345	3	5.79
8	Forrest	4	19,907	16	4.98
8	Jones	1	1,603	4	1.60
9	Harrison	2	5,299	7	3.03
9	Jackson	3	5,643	9	2.51

Based on 250 working days per year

Source: Survey of individual ambulatory surgery centers conducted April 2018; Division of Health Planning and Resource Development, Mississippi State Department of Health

Map 7-1 Ambulatory Surgery Planning Areas



701 Certificate of Need Criteria and Standards for Ambulatory Surgery Services

Should MSDH receive a CON application regarding the acquisition and/or otherwise control of major medical equipment or the provision of a service for which specific CON criteria and standards have not been adopted, the application shall be deferred until MSDH has developed and adopted CON criteria and standards. If MSDH has not developed CON criteria and standards within 180 days of receiving a CON application, the application will be reviewed using the general CON review criteria and standards presented in the *Mississippi Certificate of Need Review Manual* and all adopted rules, procedures, and plans of MSDH.

701.01 Policy Statement Regarding Certificate of Need Applications for Ambulatory Surgery Services

- 1. <u>Ambulatory Surgery Planning Areas (ASPAs):</u> MSDH shall use the Ambulatory Surgery Planning Areas as outlined on Map 7-1 of this Plan for planning and CON decisions. The need for ambulatory surgery facilities in any given ASPA shall be calculated independently of all other ASPAs.
- 2. Ambulatory Surgery Facility Service Areas: An applicant's Ambulatory Surgery Facility Service Area must have a population base of approximately 60,000 within thirty (30) minutes normal driving time or twenty-five (25) miles, whichever is greater, of the proposed/established facility. Note: Licensure standards require a freestanding facility to be within fifteen (15) minutes traveling time of an acute care hospital and a transfer agreement with said hospital must be in place before a CON may be issued. Additionally, the ambulatory surgery facility service area must have a stable or increasing population.
- 3. <u>Definitions:</u> The Glossary of this Plan includes the definitions in the state statute regarding ambulatory surgery services.
- 4. <u>Surgeries Offered:</u> MSDH shall not approve single service ambulatory surgery centers. Only multi-specialty ambulatory surgery center proposals may be approved for a CON.
- 5. <u>Minimum Surgical Operations:</u> The minimum of 1,000 surgeries required to determine need is based on five (5) surgeries per operating room per day x five (5) days per week x fifty (50) weeks per year x eighty percent (80%) utilization rate.
- 6. <u>Present Utilization of Ambulatory Surgery Services:</u> MSDH shall consider the utilization of existing services and the presence of valid CONs for services within a given ASPA when reviewing CON applications.
- 7. Optimum Capacity: The optimum capacity of an ambulatory surgery facility is 800 surgeries per operating room per year. MSDH shall not issue a CON for the establishment or expansion of an additional facility (ies) unless the existing facilities within the ASPA have performed in aggregate at least 800 surgeries per operating room per year for the most recent twelve (12) month reporting period, as reflected in data supplied to and/or verified by MSDH. MSDH may collect additional information it deems essential to render a decision regarding any application. Optimum capacity is based on four (4) surgeries per operating room per day x five (5) days per week x fifty (50) weeks per year x eighty-percent (80%) utilization rate.

- 8. <u>Conversion of Existing Service</u>: Applications proposing the conversion of existing inpatient capacity to hospital affiliated ambulatory surgical facilities located within the hospital shall receive approval preference over detached or freestanding ambulatory surgical facilities if the applicant can show that such conversion is less costly than new construction and if the application substantially meets other adopted criteria.
- 9. <u>Construction/Expansion of Facility:</u> Any applicant proposing to construct a new facility or major renovation to provide ambulatory surgery must propose to build/renovate no fewer than two (2) operating rooms.
- 10. <u>Indigent/Charity Care:</u> The applicant shall be required to provide a "reasonable amount" of indigent/charity care as described in Chapter 1 of this Plan.

701.02 Certificate of Need Criteria and Standards for Ambulatory Surgery Services

MSDH will review applications for a CON for new ambulatory surgery facilities, as defined in Mississippi law, under the statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972 Annotated, as amended. MSDH will also review applications submitted for CON_in accordance with the rules and regulations in the *Mississippi Certificate of Need Review Manual*; all adopted rules, procedures, and plans of MSDH; and the specific criteria and standards listed below.

Ambulatory surgery services require CON review when the establishment or expansion of the services involves a capital expenditure in excess of \$2,000,000. In addition, the offering of ambulatory surgery services is reviewable if the proposed provider has not provided those services on a regular basis within twelve (12) months prior to the time such services would be offered, regardless of the capital expenditure.

Need Criteria 1: Minimum Surgeries

The applicant shall demonstrate that the proposed ambulatory surgery facility shall perform a minimum average of 1,000 surgeries per operating room per year.

Need Criteria 2: Minimum Population

The applicant must document that the proposed Ambulatory Surgery Facility Service Area has a population base of approximately 60,000 within 30 minutes travel time.

Need Criteria 3: Present Utilization of Ambulatory Surgery Services

The applicant proposing to offer ambulatory surgery services shall document that the existing facilities in the ambulatory surgery planning area have been utilized for a minimum of 800 surgeries per operating room per year for the most recent_twelve (12) month reporting period as reflected in data supplied to and/or verified by MSDH. MSDH may collect additional information it deems essential to render a decision regarding any application.

Need Criteria 4: Affirmation of Provision of Surgical Services

The applicant must affirm that the proposed program shall provide a full range of surgical services in general surgery.

Need Criteria 5: Financial Feasibility

The applicant must provide documentation that the facility will be economically viable within two (2) years of initiation.

Need Criteria 6: Letters of Support

The proposed facility must show support from the local physicians who will be expected to utilize the facility.

Need Criteria 7: Staffing Requirements

Medical staff of the facility must live within a twenty-five (25) mile radius of the facility.

Need Criteria 8: Transfer Agreements/Follow-Up Services

The proposed facility must have a formal agreement with a full service hospital to provide services which are required beyond the scope of the ambulatory surgical facility's programs. The facility must also have a formal process for providing follow-up services to the patients (e.g., home health care, outpatient services) through proper coordination mechanisms.

Need Criteria 9: Indigent/Charity Care

The applicant shall affirm that the applicant will provide a "reasonable amount" of indigent/charity care by stating the amount of indigent/charity care the applicant intends to provide.

702 Home Health Care

Mississippi licensure regulations define a home health agency as: a public or privately owned agency or organization, or a subdivision of such an agency or organization, properly authorized to conduct business in Mississippi, which is primarily engaged in providing to individuals at the written direction of a licensed physician, in the individual's place of residence, skilled nursing services provided by or under the supervision of a registered nurse licensed to practice in Mississippi, and one or more of the following additional services or items:

- 1. Physical, occupational, or speech therapy
- 2. Medical social services
- 3. Home health aide services
- 4. Other services as approved by the licensing agency
- 5. Medical supplies, other than drugs and biologicals, and the use of medical appliances; or
- 6. Medical services provided by a resident in training at a hospital under a teaching program of such hospital."

All skilled nursing services and the services listed in items 1 through 4 must be provided directly by the licensed home health agency. For the purposes of this *Plan*, "directly" means either through an agency employee or by an arrangement with another individual not defined as a health care facility in Section 41-7-173 (h), Mississippi Code 1972, as amended. The requirements of this paragraph do not apply to health care facilities which had contracts for the above services with a home health agency on January 1, 1990.

702.01 Home Health Status

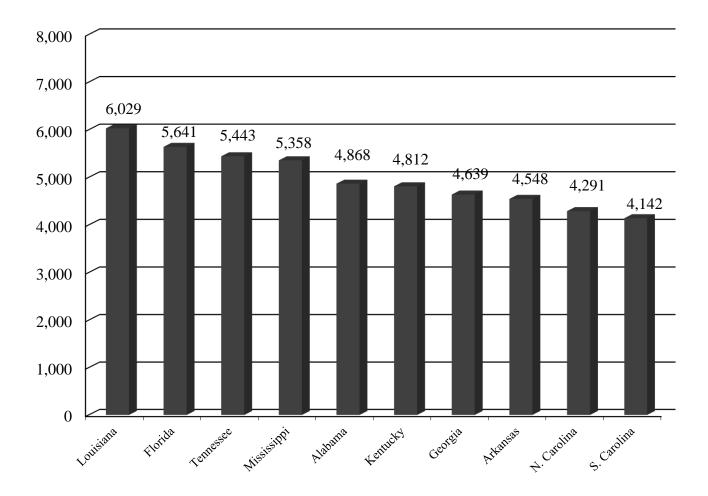
The 2016 Report on Home Health Agencies (the latest available) indicated that 56,051 Mississippians received home health services during the year. The reported noted there were 2,024,397 home health care visits made in 2016 in Mississippi. Each patient (all payor sources) received an average of thirty-four (34) visits.

Table 7-3 Medicare Home Health Statistics in the Ten-State Region January 1, 2016 – December 31, 2016

	2016 Total Home Health Visits	Total Home Health Claims	Total Home Health Payments	Total Home Health Patients	Average Home Health Payment per Patient	Average Visits per Patient
Region Total	31,749,241	1,837,640	\$4,867,820,107	945,751	\$5,147	34
Alabama	2,593,834	152,665	361,674,479	74,299	\$4,868	35
Arkansas	1,225,853	71,340	168,094,540	36,963	\$4,548	33
Florida	12,150,926	611,951	1,855,186,730	328,895	\$5,641	37
Georgia	2,383,617	147,280	392,174,285	84,532	\$4,639	28
Kentucky	1,798,752	112,715	278,384,370	57,858	\$4,812	31
Louisiana	2,925,397	185,354	406,847,630	67,485	\$6,029	43
Mississippi	2,024,397	133,948	300,330,665	56,051	\$5,358	36
North Carolina	2,654,532	174,679	457,761,772	106,679	\$4,291	25
South Carolina	1,418,020	93,116	243,526,027	58,798	\$4,142	24
Tennessee	2,573,913	154,592	403,839,609	74,191	\$5,443	35

Source: Palmetto GBA – Medicare Statistical Analysis Department, HCIS (Health Care Information System), December 2017

Figure 7-1 Medicare - Average Home Health Payments



Source: Palmetto GBA - Medicare Statistical Analysis Department, HCIS (Health Care Information System), December 2017

703 Certificate of Need Criteria and Standards for Home Health Agencies/Services

Should MSDH_receive a CON application regarding the acquisition and/or otherwise control of major medical equipment or the provision of a service for which specific CON criteria and standards have not been adopted, the application shall be deferred until MSDH_has developed and adopted CON criteria and standards. If MSDH has not developed CON criteria and standards within 180 days of receiving a CON application, the application will be reviewed using the general CON review criteria and standards presented in the *Mississippi Certificate of Need Review Manual* and all adopted rules, procedures, and plans of MSDH.

703.01 Policy Statement Regarding Certificate of Need Applications for the Establishment of a Home Health Agency and/or the Offering of Home Health Services

- 1. <u>Service Areas</u>: The need for home health agencies/services shall be determined on a county-by county basis.
- 2. <u>Determination of Need</u>: A possible need for home health services may exist in a county if for the most recent calendar year available that county had fewer home health care visits per 1,000 elderly (65+) population than the average number of visits received per 1,000 elderly (65+) in the "ten-state region" consisting of Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Mississippi, North Carolina, South Carolina, and Tennessee. That number is currently 31,794,241 as shown in Table 7-3 (2016 is the most recent data available).
- 3. <u>Unmet Need</u>: If it is determined that an unmet need exists in a given county, the unmet need must be equivalent to fifty (50) patients in each county proposed to be served. Based on 2016 data 31,749,241 visits approximates a Region Total of thirty four (34) visits per patient.
- 4. All CON applications for the establishment of a home health agency and/or the offering of home health services shall be considered substantive and will be reviewed accordingly.

703.02 Certificate of Need Criteria and Standards for the Establishment of a Home Health Agency and/or the Offering of Home Health Services

If the present moratorium were removed or partially lifted, MSDH would review applications for a CON for the establishment of a home health agency and/or the offering of home health services under the applicable statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972, as amended. MSDH will also review applications submitted for CON according to the general criteria as listed in the *Mississippi Certificate of Need Review Manual*; all adopted rules, procedures, and plans of MSDH; and the specific criteria and standards listed below.

The development or otherwise establishment of a home health agency requires CON. The offering of home health services is reviewable if the proposed provider has not provided those services on a regular basis within the period of twelve (12) months prior to the time such services would be offered.

Need Criteria 1: Establishment of Need

The applicant shall document that a possible need for home health services exists in each county proposed to be served using the methodology contained in this section of the *Plan*.

Need Criteria 2: Home Health Service Area Boundaries

The applicant shall state the boundaries of the proposed home health service area in the application.

Need Criteria 3: Unmet Need

The applicant shall document that each county proposed to be served has an unmet need equal to fifty (50) patients, using a ratio of 31,749,241 patient total home health visits equals approximately 34 average visits per patient.

Need Criteria 4: Home Office of New Home Health Agency

The applicant shall document that the home office of a new home health agency shall be located in a county included in the approved service area of the new agency. An existing agency receiving CON approval for the expansion of services may establish a sub-unit or branch office if such meets all licensing requirements of the Division of Licensure.

Need Criteria 5: Application Requirements

The application shall document the following for each county to be served:

- a. Letters of intent from physicians who will utilize the proposed services.
- b. Information indicating the types of cases physicians would refer to the proposed agency and the projected number of cases by category expected to be served each month for the initial year of operation.
- c. Information from physicians who will utilize the proposed service indicating the number and type of referrals to existing agencies over the previous twelve (12) months.
- d. Evidence that patients or providers in the area proposed to be served have attempted to find services and have not been able to secure such services.
- e. Projected operating statements for the first three years, including:
 - i. Total cost per licensed unit;
 - ii. Average cost per visit by category of visit; and
 - iii. Average cost per patient based on the average number of visits per patient.

Need Criteria 6: Difference in Existing Services Already Provided

Information concerning whether proposed agencies would provide services different from those available from existing agencies.

703.03 Statistical Need Methodology for Home Health Services

The methodology used to calculate the average number of visits per 1,000 elderly (65+) in the ten state region consist of the following:

- 1. The ten-state region consists of Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Mississippi, North Carolina, South Carolina, and Tennessee.
- 2. The 2023 projected population aged 65 and older estimates from each state.

- 3. Table 7-3 showing the average number of Medicare paid home health visits for the ten-state region, according to 2016 data from Palmetto GBA Medicare Statistical Analysis Department of the Centers for Medicare and Medicaid Services. Figure 7-1 shows the total number of Medicare paid home health payments in the ten-state region.
- 4. In 2016, the region average of home health visits was 31,749,241. An average patient in the region received thirty-four (34) home health visits. Therefore 31,749,241, visits equal 34 patients. Note: The Mississippi average for 2016 was 2,024,397 visits (Medicare reimbursed) and an averaged patient received thirty-six (36) visits.

704 End Stage Renal Disease

End stage renal disease (ESRD) describes the loss of kidney function from chronic renal failure to the extent that the remaining kidney function will no longer sustain life. The kidney's function of filtering waste products from the blood and removing fluid and salts from the body is essential for life; consequently, if untreated, end stage renal disease results in death.

ESRD treatment generally consists of either a kidney transplant or dialysis. Dialysis treatment consists of either peritoneal dialysis or hemodialysis. Peritoneal dialysis, uses a dialyzing fluid which is placed in the abdominal cavity through a plastic tube (catheter), and waste products (fluid and salts) exchange across the peritoneal membrane between the patient's blood and the dialyzing fluid. Hemodialysis is the process by which an artificial kidney machine "washes" metabolic waste products from the bloodstream and removes fluids and salts.

Both hemodialysis and peritoneal dialysis mimic the function normally performed by the kidney. Dialysis can be done by the patient and an assistant in the home, in a facility, or by professional staff in a hospital or limited care facility. Mississippi has 74 ESRD facilities and 10 Satellite ESRD facilities providing maintenance dialysis services as of FY 2018 Map 7-1 shows the facility locations and Table 7-4 shows the number of existing and CON approved ESRD facilities by county.

Kidney transplantation is the treatment of choice for most patients with end stage renal failure. Unfortunately, suitable kidneys will probably never be available in the number that would be required to treat everyone with this mode of therapy. In kidney transplantation, a healthy kidney is removed from a donor and placed into an ESRD patient. Donors for kidney transplantation may come either from a close relative, such as a sibling or parent, or from an emotionally connected donor, such as a spouse or close associate. Kidneys may also be obtained from cadaver donors who have the closest matching tissue type. Living donors are preferred because they function longer than cadaver kidneys – thirty (30) years for a living donor versus fifteen (15) years for a cadaver kidney.

The University of Mississippi Medical Center, the only kidney transplant program in the state, performed 103 cadaver and zero living-donor transplants during the calendar year 2013. It is certified by membership in the United Network of Organ Sharing, a private agency under contract from the Health Care Financing Administration. Transplant results are comparable to those with transplant programs with similar population basis and can be viewed on the Internet under www.ustransplants.org. Approximately, 100 additional transplants in Mississippi residents are performed in neighboring states.

Table 7-4
Number of Existing and CON Approved ESRD Facilities by County

Number of Existing and CON Approved ESRD Facilities by County Number of Certified				
	and CON Approved			
ESRD Facilities by County	Stations			
Adams	31			
RCG of Natchez	31			
A1	22			
Alcorn RCG of Corinth	22 22			
RCG OF COLUMN	22			
Attala	20			
FMC Kosciusko	20			
Bolivar	32			
Fresenius Kidney Care	32			
Claiborne	10			
Fresenius Kidney Care - Port Gibson	10			
Clada	12			
Clarke	13 13			
Pachuta Dialysis Unit	13			
Clay	14			
FMC- West Point	14			
Tivie West I out	14			
Coahoma	40			
RCG of Clarksdale	40			
Copiah	30			
BMA Hazlehurst	13			
Hazelhurst Dialysis	17			
Covington	23			
Collins Dialysis Unit	23			
DeSoto	49			
Fresenius Kidney Care*	49			
Forrest	40			
Hattiesburg Dialysis Unit	60 60			
Hatticsoulg Dialysis Utilit	UU			
George	16			
Lucedale Dialysis	16			
Grenada	28			
RCG of Grenada	28			
Hancock	20			
FMC- South Miss Kidney Center - Diamondhead (Bay St. Louis)	20			

^{*}Satellite ESRD Facility

Table 7-4 (continued)
Number of Existing and CON Approved ESRD Facilities by County

ESRD Facilities by County	Number of Certified and CON Approved Stations	
Harrison	101	
FMC-South Miss Kidney Center - Biloxi	19	
FMC-South Miss Kidney Center - Gulfport	20	
FMC-South Miss Kidney Center - Orange Grove	30	
FMC-South Miss Kidney Center - D'Iberville	12	
FMC-South Miss Kidney Center - North Gulfport	20	
Hinds	252	
FMC- Jackson*	38	
FMC- Mid Mississippi*	12	
FMC Southwest Jackson	33	
FMC - West Hinds County *	14	
Davita Jackson North	46	
Davita Jackson South	28	
Davita Jackson Southwest	18	
University MS Medical Center Outpatient Hemodialysis	40	
University MS Medical Center Pediatric Nephrology Facility	23	
Holmes	22	
Davita Renal Care of Lexington	22	
Humphreys	9	
RCG of Belzoni	9	
Itawamba	13	
Davita Itawamba County Dialysis	13	
Jackson	45	
Davita Ocean Springs Dialysis	17	
Davita Singing River Dialysis	28	
Jasper	21	
Bay Springs Dialysis Unit - Bay Springs	21	
Jones	38	
Laurel Dialysis Unit	38	
Kemper	10	
FMC-Kemper County	10	
Lafayette	28 28	
RCG Oxford	28	
Lamar	14	
West Hattiesburg Clinic Dialysis*	14	
Lauderdale	75	
Fresenius Kidney Care- Meridian	65	
FMC- Lauderdale County*	10	
Lawrence	18	
Silver Creek Dialysis Unit	18	
Leake	15	
RCG- Carthage	15	

^{*}Satellite ESRD Facility

Table 7-4 (continued) Number of Existing and CON Approved ESRD Facilities by County

	Number of Certified and CON Approved		
ESRD Facilities by County	Stations		
Lee	60		
RCG of Tupelo	50		
Lee County Dialysis*	10		
Leflore	34		
RCG of Greenwood	34		
Lincoln	32		
RCG of Brookhaven	32		
Lowndes	49		
RCG of Columbus	35		
FMC - Lowndes*	14		
Madison	40		
FMC Canton	18		
Canton Renal Center	22		
Marion	30		
Columbia Dialysis Unit	30		
Marshall	20		
RCG of Holly Springs	20		
Monroe	32		
RCG of Aberdeen	32		
Montgomery	15		
RCG of Winona	15		
Neshoba	53		
Fresenius Kidney Care - Pearl River	39		
Fresenius Kidney Care- Neshoba County	14		
Newton	16		
FMC- Newton	16		
Noxubee	21		
RCG of Macon	21		
Oktibbeha	25		
RCG of Starkville	25		
Panola	30		
RCG of Sardis	30		
Pearl River	20		
Picayune Dialysis Unit	20		

^{*}Satellite ESRD Facility

Table 7-4 (continued)
Number of Existing and CON Approved ESRD Facilities by County

ESRD Facilities by County	Number of Certified and CON Approved Stations	
Perry	20	
Richton Dialysis Unit	20	
Pike	32	
RCG of McComb	32	
Rankin	59	
Fresenius Kidney Care-Rankin County Davita Brandon	35 24	
Scott	18	
FMC - Forest	18	
Sharkey	13	
FMC-Rolling Fork	13	
Simpson	18	
FMC - Magee	18	
Stone	12	
Wiggins Dialysis Unit	12	
Sunflower RCG of Indianola	21 21	
RCG of Indianoia	21	
Tate	10	
RCG- Senatobia	10	
Tunica	24	
RCG- Tunica*	24	
Union	25	
Fresenius Kidney Care- Central New Albany*	25	
, , , , , , , , , , , , , , , , , , ,		
Walthall	21	
Tylertown Dialysis Unit	21	
Warren	21	
Fresenius Kidney Care	21	
·		
Washington	52	
Mid-Delta Kidney Center	9	
Fresenius Kidney Care- Greenville	43	
Wayne	19	
Waynesboro Renal Dialysis Unit	19	
Webster	14	
RCG of Europa	14	
•		
Wilkinson	17	
RCG of Centerville	17	
Winston	17	
RCG of Louisville	17	
Yazoo	21	
FMC Yazoo City	21	
State Total	1,980	

^{*}Satellite ESRD Facility

Marshall Benton Alcorn Tishomingo Tunica **Existing Facility** Prentiss CON Approved Tippah Union Panola Lafayette Itawamba Pontotoc Coahoma Yalobusha Calhoun Quitman Bolivar Chickasaw Monroe Tallahatchie Grenada Clay Webster Carroll Mont-gomery Washington Oktibbeha Leflore Sunflower Choctaw Lowndes Attala Winston Noxubee Humphreys Holmes Issa-Yazoo Kemper Leake Neshoba Madison Scott Newton Lauderdale Hinds Rankin Smith Jasper Clarke Claiborne Copiah Simpson Jefferson Wayne Jones Covington Lincoln Lawrence Franklin Jefferson Davis Lamar Forrest Greene Marion Amite Pike Wilkinson Walthall George Pearl River Stone Source: Mississippi State Department of Health, Division of Health Facilities Licensure and Harrison Certification, May 2014. Hancock

Map 7-2 End Stage Renal Disease Facilities

704 Certificate of Need Criteria and Standards for End Stage Renal Disease Facilities

MSDH receive a CON application regarding the acquisition and/or otherwise control of major medical equipment or the provision of a service for which specific CON criteria and standards have not been adopted, the application shall be deferred until MSDH has developed and adopted CON criteria and standards. If MSDH_has not developed CON criteria and standards within 180 days of receiving a CON application, the application will be reviewed using the general CON review criteria and standards presented in the *Mississippi Certificate of Need Review Manual* and all adopted rules, procedures, and plans of MSDH.

704.01 Policy Statement Regarding Certificate of Need Application for the Establishment of End Stage Renal Disease (ESRD) Facilities

- 1. <u>Establishment of an ESRD Facility</u>: The provision or proposed provision of maintenance dialysis services constitutes the establishment of an ESRD facility if the proposed provider has not provided those services on a regular basis within the period of twelve (12) months prior to the time such services would be offered.
- 2. <u>Type of Review</u>: CON applications for ESRD services shall be considered substantive as defined under the appropriate *Mississippi State Health Plan*-
- 3. <u>ESRD Facility Service Area</u>: An ESRD Facility Service Area is defined as the area within a thirty (30) mile radius of an existing or proposed ESRD facility. ESRD Facility Service Areas, including the Service Areas of existing facilities which overlap with the proposed Service Area, shall be used for planning purposes.
- 4. <u>Utilization Definitions</u>: These utilization definitions are based upon three (3) shifts per day six (6) days per week, or eighteen (18) shifts per week. Only equipment (peritoneal or hemodialysis) that requires staff assistance for dialysis and is in operation shall be counted in determining the utilization rate. Utilization of equipment in operation less than twelve (12) months shall be prorated for the period of time in actual use.
 - a. Full Utilization: For planning and CON purposes, full (100 percent) utilization is defined as an average of 936 dialyses per station per year.
 - b. Optimum Utilization: For planning and CON purposes, optimum (65 percent) utilization is defined as an average of 608 dialyses per station per year.
 - c. Need Utilization: For planning and CON purposes, need (80 percent) utilization is defined as an average of 749 dialyses per station per year.
- 5. <u>Outstanding CONs</u>: ESRD facilities that have received CON approval but are not operational shall be considered to be operating at 50 percent, which is the minimum utilization rate for a facility the first year of operation.
- 6. <u>Utilization Data</u>: The Department may use any source of data, subject to verification by the Department, it deems appropriate to determine current utilization or projected utilization of services in existing or proposed ESRD facilities. The source of data may include, but is not limited to, Medicare Certification records maintained by the Division of Health Facilities

Licensure and Certification, ESRD Network #8 data, and Centers for Medicare and Medicaid Services (CMS) data.

- 7. <u>Minimum Expected Utilization</u>: It is anticipated that a new ESRD facility may not be able to reach optimum utilization (65 percent) of ten ESRD stations during the initial phase of operation. Therefore, for the purposes of CON approval, an application must demonstrate how the applicant can reasonably expect to have 50 percent utilization of a minimum of ten ESRD stations by the end of the first full year of operation and 65 percent utilization by the end of the third full year of operation.
- 8. <u>Minimum Size Facility</u>: No CON application for the establishment of a new ESRD facility shall be approved for less than ten (10) stations.
- 9. <u>Expansion of Existing ESRD Facilities</u>; Existing ESRD facilities may add ESRD stations as follows:
 - a. An existing ESRD facility with a CMS star rating of 1 or 2, may add ESRD stations without certificate of need review as long as the facility does not add, over the period of one (1) year, more than four (4) stations.
 - b. An existing ESRD facility with a CMS star rating of 3, may add ESRD stations without certificate of need review as long as the facility does not add, over the period of one (1) year, more than six (6) stations.
 - c. An existing ESRD facility with a CMS star rating of 4 or 5, may add ESRD stations without certificate of need review, as long as the facility does not add, over the period of one (1) year, more than eight (8) stations.

Note: An ESRD facility that has not yet been given a CMS star rating may add ESRD stations without certificate of need review as long as the facility does not add, over the period of one (1) year, more than four (4) stations.

- 10. <u>Home Dialysis Programs</u>: Each existing ESRD facility may establish or relocate a home dialysis program to any location within a 10-mile radius of the existing facility without certificate of need review; provided, however, that the facility shall submit an application for determination of non-reviewability prior to the establishment of the dialysis program. If such established or relocated home dialysis program is a freestanding program, the freestanding home dialysis program shall document that it has a back-up agreement for the provision of any necessary dialysis services with the existing ESRD facility. If an existing ESRD facility wants to create, either through establishment or relocation, more than two home dialysis program, the project shall be subject to CON review as the establishment of a new ESRD facility. Existing freestanding home dialysis programs may add home training stations as follows:
 - a. An existing freestanding home dialysis facility with a CMS star rating of 1 or 2, may add home training stations without certificate of need review as long as the facility does not add, over the period of one (1) year, more than four (4) stations.
 - b. An existing freestanding home dialysis facility with a CMS star rating of 3, may add home training stations without certificate of need review as long as the facility does not add, over the period of one (1) year, more than six (6) stations.

c. An existing ESRD facility with a CMS star rating of 4 or 5, may add home training stations without certificate of need review, as long as the facility does not add, over the period of one (1) year, more than eight (8) stations.

Note: An existing freestanding home dialysis facility that has not yet been given a CMS star rating may add home training stations without certificate of need review as long as the facility does not add, over the period of one (1) year, more than eight (8) stations.

- 11. <u>Establishment of Satellite ESRD Facilities</u>: Any existing ESRD facility which reaches a total of 30 ESRD stations, may establish a ten (10) station satellite facility. If a proposed satellite ESRD facility is to be located more than one (1) mile from the existing facility, a certificate of need must be obtained by the facility prior to the establishment of the satellite facility.
- 12. <u>Non-Discrimination</u>: An applicant shall affirm that within the scope of its available services, neither the facility nor its staff shall have policies or procedures which would exclude patients because of race, color, age, sex, or ethnicity.
- 13. <u>Indigent/Charity Care</u>: An applicant shall be required to provide a "reasonable amount" of indigent/charity care as described in Chapter 1 of this *Plan*.
- 14. <u>Staffing</u>: The facility must meet, at a minimum, the requirements and qualifications for staffing as contained in 42 CFR § 494.140. In addition, the facility must meet all staffing requirements and qualifications contained in the service specific criteria and standards.
- 15. <u>Federal Definitions</u>: The definitions contained in 42 CFR § 494.10 shall be used as necessary in conducting health planning and CON activities.
- 16. <u>Affiliation with a Renal Transplant Center</u>: ESRD facilities shall be required to enter into a written affiliation agreement with a renal transplant center.

704.02 Certificate of Need Criteria and Standards for End Stage Renal Disease (ESRD) Facilities

MSDH will review applications for a CON for the establishment of an ESRD facility under the applicable statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972, as amended. MSDH will also review applications for CON according to the general criteria as listed in the *Mississippi Certificate of Need Review Manual*; all adopted rules, procedures, and plans of MSDH; and the specific criteria and standards listed below.

When a provider proposes to offer ESRD services in an ESRD facility service area where he does not currently provide services or proposes to transfer an existing ESRD unit(s) from a current location into a different ESRD facility service area, it will constitute the establishment of a new ESRD health care facility. (Note: The transfer of dialysis stations from an existing ESRD facility to any other location is a relocation of a health care facility or portion thereof and requires CON review. Likewise, new dialysis stations placed into service at a site separate and distinct from an existing ESRD facility constitutes the establishment of a new health care facility and requires CON review. Dialysis stations placed into service in an individual patient's home or residence, solely for the treatment of the individual patient concerned, are exempt from this regulation.)

704.02.01 Establishment of an End Stage Renal Disease (ESRD) Facility

Need Criterion 1: For Establishment of New ESRD Facilities

An applicant proposing the establishment of a limited care renal dialysis facility or the relocation of a portion of an existing ESRD facility's dialysis stations to another location shall demonstrate, subject to verification by the Mississippi State Department of Health, that each individual existing ESRD facility in the proposed ESRD Facility Service Area has maintained a minimum annual utilization rate of eighty (80) percent.

Need Criterion 2: For Expansion of Existing ESRD Facilities

- a. Expansion of Existing ESRD Facilities Non-Satellite: In the event that an existing ESRD facility (that is not a satellite facility less than two (2) years in existence) proposes to add more stations than what is outlined in ESRD Policy Statement 9, then the facility must apply for a certificate of need, and shall document that it has maintained, or can project a minimum annual utilization rate of sixty-five percent (65%) for the 12 months prior to the month of the submission of the CON application. NOTE: ESRD Policy Statements 3 and Need Criteria 1, do not apply to applications for the expansion of existing ESRD facilities.
- b. Expansion of Existing ESRD Facilities Satellite: In the event that an existing ESRD facility (that is a satellite facility in operation two years or less), proposes to add more stations than what is outlined in ESRD Policy Statement 9, then the facility must apply for a certificate of need, and shall document that it has maintained or can project through, for example, but not necessarily limited to, patient support letters, the distance between the patient's residence or transportation source and the facility, and/or transportation or patient support concerns, a minimum annual utilization rate of sixty-five percent (65%). NOTE: ESRD Policy Statement 3 and Need Criteria 1 do not apply to applications for the expansion of existing ESRD facilities.

Need Criterion 3: For Establishment of ESRD Satellite Facilities

In order for a thirty (30) station ESRD facility to be approved for the establishment of a ten (10) station satellite facility through the transfer and relocation of existing stations within a five mile radius or less from the existing facility, the facility must (a) document that it has maintained a minimum annual utilization rate of fifty-five percent (55%) for the twelve (12) months prior to the month of the submission of the CON application; (b) justify the need for the project, which may include, but is not limited to, physical or space limitations at the existing facility; and (c) document that it is more cost effective to establish a satellite facility than to expand the existing facility. If the proposed satellite facility will be established at a location between a five and thirty (30) mile radius of the existing facility, the facility must (a) document that it has maintained a minimum annual utilization rate of fifty-five percent (55%) for the twelve (12) months prior to the month of the submission of the CON application; (b) justify the need for the project, which may include, but is not limited to, physical or space limitations at the existing facility; and (c) document that it is more cost effective to establish a satellite facility than to expand the existing facility; and (d) demonstrate that the proposed satellite facility's location is not within thirty miles of an existing facility without obtaining the existing facility's written support. NOTE: ESRD Policy Statements 2, 4, 5 and 6, and Need Criterion 1, do not apply to applications for the establishment of satellite ESRD facilities. An ESRD satellite facility established under this Need Criterion 3 shall not be used or considered for purposes of establishing or determining an ESRD Facility Service Area.

Need Criterion 4: Number of Stations

The applicant shall state the number of ESRD stations that are to be located in the proposed facility. No new facility shall be approved for less than ten (10) dialysis stations.

Need Criterion 5: Minimum Utilization

The application shall demonstrate that the applicant can reasonably expect to meet the minimum utilization requirements as stated in ESRD Policy Statement #10.

Need Criterion 6: Minimum Services

The application shall affirm that the facility will provide, at a minimum, social, dietetic, and rehabilitative services. Rehabilitative services may be provided on a referral basis.

Need Criterion 7: Access to Needed Services

The application shall affirm that the applicant will provide for reasonable access to equipment/facilities for such needs as vascular access and transfusions required by stable maintenance ESRD patients.

Need Criterion 8: Access to Needed Services

The application shall affirm that the applicant will provide for reasonable access to equipment/facilities for such needs as vascular access and transfusions required by stable maintenance ESRD patients.

Need Criterion 9: Home Training Program

The application shall affirm that the applicant will make a home training program available to those patients who are medically eligible and receptive to such a program. The application shall affirm that the applicant will counsel all patients on the availability of and eligibility requirements to enter the home/self-dialysis program.

Need Criterion 10: Indigent/Charity Care

The application shall affirm that the applicant will provide a "reasonable amount" of indigent/charity care. The application shall also state the amount of indigent/charity care the applicant intends to provide.

Need Criterion 11: Facility Staffing

The application shall describe the facility's staffing by category (i.e., registered nurse, technologist, technician, social worker, dietician) as follows:

- a. Qualifications (minimum education and experience requirements)
- b. Specific Duties
- c. Full Time Equivalents (FTE) based upon expected utilization

Need Criterion 12: Staffing Qualifications

The applicant shall affirm that the staff of the facility will meet, at a minimum, all requirements and qualifications as stated in 42 CFR, Subpart D § 494.140.

Need Criterion 13: Staffing Time

a. The applicant shall affirm that when the unit is in operation, at least one (1) R.N. will be on duty. There shall be a minimum of two (2) persons for each dialysis shift, one of whom must be an R.N.

- b. The applicant shall affirm that the medical director or a designated physician will be onsite or on-call at all times when the unit is in operation. It is desirable to have one other physician to supplement the services of the medical director.
- c. The applicant shall affirm that when the unit is not in operation, the medical director or designated physician and a registered nurse will be on-call.

Need Criterion 14: Data Collection

The application shall affirm that the applicant will record and maintain, at a minimum, the following utilization data and make this data available to the Mississippi State Department of Health as required. The time frame for the submission of the utilization data shall be established by the Department.

- a. Utilization data, e.g., days of operation, shifts, inventory and classification of all stations, number of patients in dialysis, transplanted, or expired.
- b. The number of charity/indigent patients (as defined in this *Plan*) served by the facility and the number of dialysis procedures provided to these patients free of charge or at a specified reduced rate.

Need Criterion 15: Staff Training

The application shall affirm that the applicant will provide an ongoing program of training in dialysis techniques for nurses and technicians at the facility.

Need Criterion 16: Scope of Privileges

The applicant shall affirm that the facility shall provide access to doctors of medicine or osteopathic medicine licensed by the State of Mississippi who possess qualifications established by the governing body of the facility.

Need Criterion 17: Affiliation with a Renal Transplant Center

The applicant shall affirm that within one year of commencing operation the facility will enter into an affiliation agreement with a transplantation center. The written agreement shall describe the relationship between the transplantation facility and the ESRD facility and the specific services that the transplantation center will provide to patients of the ESRD facility. The agreement must include at least the following:

- a. time frame for initial assessment and evaluation of patients for transplantation;
- b. composition of the assessment/evaluation team at the transplant center;
- c. method for periodic re-evaluation;
- d. criteria by which a patient will be evaluated and periodically re-evaluated for transplantation; and
- e. signatures of the duly authorized persons representing the facilities and the agency providing the services.
- f. Furthermore, the application shall affirm that the applicant understands and agrees that failure to comply with this criterion may (after due process) result in revocation of the Certificate of Need.

704.02.02 Establishment of a Renal Transplant Center

Need Criterion 1:

The applicant shall document that the proposed renal transplant center will serve a minimum population of 3.5 million people.

Need Criterion 2:

The applicant shall document that the proposed facility will provide, at a minimum, the following:

- a. medical-surgical specialty services required for the care of ESRD transplant patients;
- b. acute dialysis services;
- c. an organ procurement system;
- d. an organ preservation program; and
- e. a tissue typing laboratory.

Need Criterion 3:

The applicant shall document that the facility will perform a minimum of 25 transplants annually.